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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,248	03/26/2001	Peter Baumann	89491/201	8759

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EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	13

DATE MAILED: 10/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/816,248	BAUMANN ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-48* is/are pending in the application.

4a) Of the above claim(s) *6-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. This action is in response to Paper No. 12, filed July 19, 2002. Claims 1-5 have been canceled and claims 37-48 have been added. Any rejections not reiterated herein are hereby withdrawn. Applicants arguments presented in the response of Paper No. 12 have been fully considered but are not persuasive to overcome all grounds of rejection. This action is made final.

2. Claims 37, 40, 41, 44, 45, 46, and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 37 is drawn to an isolated naturally occurring protein encoded by a variant of a full length human protection of telomere 1 (hPot 1) transcript. Claims 40, 41, 44, 45, 46 and 47 appear to be drawn to proteins that are encoded by variants of a nucleic acid encoding a protein having 85% identity to SEQ ID NO: 15 or 17 or which differ from SEQ ID NO: 15 or 17 by about no more than 20 amino acid substitutions, deletions, additions or insertions. The specification teaches 2 splice variants of the human Pot1 protein, wherein said variants consist of SEQ ID NO: 15 and 17. However, the specification does not disclose any additional splice variants and does not disclose any other types of variants of the human Pot1 protein. Accordingly, while variants of the hPot 1 protein having the amino acid sequence of SEQ ID NO: 15 and 17 meet the written description requirements of 35 U.S.C. 112, first paragraph, the specification does not disclose and fully characterize the genus of any variant of the protein of SEQ ID NO: 13. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant

must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only 2 members of the broadly claimed genus of splice variants of the human Pot1 protein have been defined in terms of their structure. The recitation in the claims of a variant of the protein of SEQ ID NO: 13 is so broad as to not provide a meaningful structural limitation to the claims. As broadly defined in the specification, variants include proteins which may comprise any number of additions, deletions or substitutions in the amino acid sequence of

SEQ ID NO: 13. The claims do not set forth the identity which might be shared between the variant and SEQ ID NO: 13. Furthermore, the claims do not set forth specific splice sites within SEQ ID NO: 13 which would result in the generation of additional splice variants. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g., in terms of a specific functional activity). In the instant case, no such identifying characteristics have been provided for any additional variants. Specifically, the claims do not provide a functional limitation for the claimed proteins. Accordingly, the claims include variants of the protein of SEQ ID NO: 13 which do not have the ability to bind single-stranded telomeric DNA. Yet, the specification has not disclosed any variants having functional properties distinct from the proteins of SEQ ID NO: 13, 15 or 17. The broadest reasonable interpretation of the claims indicates that the claims are inclusive of a large genus of polymorphic variants and splice variants of the hPot1 protein. However, the specification does not exemplify any polymorphisms in the hPot1 protein. While one could contemplate an amino acid substitution, deletion or addition at each and every position in the hPot1 protein, such alterations are not considered to be equivalent to specific naturally occurring allelic variants of the hPot1 protein. Accordingly, knowledge of the sequence of the wild-type hPot1 protein does not allow the skilled artisan to envision all of the contemplated polymorphisms and splice variants encompassed by the claimed genus of proteins. Therefore, Applicants have not provided sufficient evidence that they were in possession, at the time of filing, of the invention as it is broadly claimed and thus the written description requirement has

not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Response to arguments:

In the response of Paper No. 12, Applicants traverse this rejection by stating that the specification teaches that "the invention provides isolate Pot 1 proteins having the sequence set forth in SEQ ID NO: 13, SEQ ID NO: 15, SEQ ID NO: 17, SEQ ID NO: 9 or SEQ ID NO: 11. Variants of these proteins are capable of binding single-stranded telomeric DNA...The invention also provides an isolated, naturally occurring, variant of a protein having the sequence set forth in SEQ ID NO: 13 or SEQ ID NO: 9, which may be a spice variant..." Applicants thereby conclude that "the specification conveys with reasonable clarity to one of skill in the art that the instant invention provides variants of SEQ ID NO: 13."

Applicants arguments have been fully considered but are not persuasive for the following reasons. It is first noted that the above rejection acknowledges that the specification has adequately described the variants of hPot 1 (SEQ ID NO: 13) consisting of the amino acid sequence of SEQ ID NO: 15 and 17. It is further noted that SEQ ID NO: 9 and SEQ ID NO: 11 are not variants encoded by a full length human Pot 1 transcript since these proteins are derived from S. pombe. Secondly, a statement in the specification that Applicants intend to claim variants of hPot 1 is not equivalent to providing an adequate structural description of such

variants. Furthermore, such a disclosure does not indicate that Applicants were in possession of a representative number of variants at the time the invention was made. Applicants have identified 2 splice variants of hPot 1. However, the claims encompass a potentially large number of variants that are not defined in terms of their structural properties and/or are not defined by their functional properties. For example, claim 37 is inclusive of proteins having any functional attributes which are encoded by a variant which differs in any manner (e.g., by substitution at an unlimited number of nucleotide positions, by deletion of any number of nucleotides or by insertion of any number of nucleotides) from a full length human Pot 1 transcript, which is not defined in terms of any of its structural properties. Clearly, the teachings in the specification of 2 splice variants is not representative of the large genus of proteins encompassed by the claims.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37, 40, 41, 44, 45-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Isogai (Accession No. BAA91568, February 22, 2000).

Isogai et al disclose a protein having an amino acid sequence identical to the protein of SEQ ID NO: 13. The protein of Isogai also comprises an amino acid sequence identical to instant SEQ ID NO: 5 (see amino acids 1-109 of the protein of Isogai). The protein of Isogai comprises

an amino acid sequence having at least 93% identity with SEQ ID NO: 15 and having at least 96% identity with SEQ ID NO: 17.

RESPONSE TO ARGUMENTS:

In the response of Paper No. 12, Applicants traverse this rejection by arguing that while Isogai teaches a protein having an amino acid sequence identical to SEQ ID NO: 13, the reference does not teach variants of SEQ ID NO: 13. This argument has been fully considered but is not persuasive because the claims are not limited to variants of SEQ ID NO: 13. In particular, the claims are not limited to splice variants or variants which differ in any specific manner from SEQ ID NO: 13. Rather, the claims are broadly drawn to proteins encoded by **any variant** of **any full length human protection of telomere-1 (hPot 1) transcript**. Thereby the claims are considered to be inclusive of the full length proteins of Isogai encoded by an undefined variant of an undefined full length hPot 1 transcript.

4. THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Claims 38-45 and 47-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38-41 are indefinite over the recitation of "said variant has the amino acid sequence set forth in SEQ ID NO: 15". Claims 38-41 depend from claim 37 wherein the "variant" is defined as a transcript. Thereby, it is unclear as to what is intended to be meant by

the variant comprising the amino acid sequence of SEQ ID NO: 15. It is unclear as to whether "the variant" is intended to refer to a variant of a nucleic acid transcript or a variant of a protein. Similarly, claims 42-45 are indefinite over the recitation of "the variant". It appears that each of the claims should be amended to recite "wherein said isolated naturally occurring protein" in place of "said variant".

Claims 40 and 41 are indefinite and vague because they are not further limiting from the claim from which they depend. While claim 38 appears to be limited to a protein having the amino acid sequence of SEQ ID NO: 15, claims 40 and 41 are more broadly drawn to proteins having 85% identity with SEQ ID NO: 15 (claim 40) and proteins which differ from SEQ ID NO: 15 by not more than about 20 amino acid substitutions, deletions or additions. It appears that claims 40 and 41 should depend from claim 37 rather than claim 38. Similarly, claims 44-45 are indefinite because they are not further limiting from claim 42. It is suggested that claims 44-45 be amended to refer back to claim 37 rather than claim 42.

Claims 47 and 48 are indefinite over the recitation of "a fragment of said variant". Claims 47 and 48 depend from claim 37 wherein the variant is defined as a transcript. However, in claims 47 and 48 the variant has the property of binding single-stranded telomeric DNA and thereby is considered to be a protein. Thereby it is unclear as to what variant is being referred to and whether the variant is a transcript or a protein.

Claim 48 is indefinite and confusing because the claim refers to a fragment of a protein and also refers to a fragment that encodes an amino acid sequence. While it is well accepted that

nucleic acids encode for proteins, it is unclear as to what is intended to be meant by a protein fragment encoding for an amino acid sequence.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

October 17, 2002

Carla Myers

CARLA J. MYERS
PRIMARY EXAMINER